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Long-term Quality of Life and Chronic Pain after Inguinal Hernia Repair in Women

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Abstract

Background: Groin hernias in women are rare and most published studies only assess different operation techniques and the associated recurrence rates. Information about chronic postoperative pain and quality of life following groin hernia repair in women is sparse.

Methods: In total, 24 female patients following groin hernia repair were included in this prospective study. Median follow-up was 6.25 years. The Core Outcome Measure Index (COMI) hernia questionnaire was used to assess quality of life and chronic postoperative pain.

Results: The COMI-hernia total score and COMI-hernia pain score both decreased significantly after surgery (p=0.00018 and p=0.0095, respectively). Both scores correlated with patients' satisfaction. High preoperative COMI-hernia total score and low American Society of Anaesthesiologists (ASA) score were identified as risk factors for an adverse outcome after surgery. Similarly, low ASA score was shown as a risk factor for postoperative high COMI-hernia pain score.

Conclusions: Risk factors for adverse outcome after groin hernia repair seem to be different between males and females. Patient's fitness prior to surgery seems to inversely correlate with outcome after groin hernia repair in females.

Keywords: Inguinal hernia repair; Quality assessment; Quality of life; Chronic pain; Core outcome measure index; Patient satisfaction

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Introduction

Groin hernia repair is one of the most frequently performed operations in general surgery and the majority of affected patients are males [1]. Only 8% of all groin hernia repairs are performed in females [2], and outcome data after groin hernia repair in women are relatively rare [3]. There are important differences between groin hernias in women and men. Groin hernias are less common in women with an incidence of 0.3% compared to 2-5% in men [4]. Femoral hernias account for about one third of all groin hernias in females compared to only 2.4% in males [4]. This may be explained by anatomical differences in the inguinal region between males and females [5].

These differences could imply that treatment in women may have to be different from treatment in men. However, the optimal treatment of groin hernias in women remains controversial [6]. There have not been any systematic reviews or randomized controlled trials, which deal exclusively with the treatment of groin hernias in women. The European Hernia Society recommends to perform a – preferably endoscopic - preperitoneal repair in women due to the high frequency of femoral hernias [7]. This recommendation is mainly based on two epidemiological studies from national databases and therefore the grade of recommendation is low (D) [3,8]. The vast majority of published studies about groin hernia repair in women compare different surgical techniques and assess the concomitant recurrence rate as primary outcome [3,4,8-13]. Also the latest international guidelines from Hernia Surg group recommend a preperitoneal repair in women [14].

However, since the routine use of mesh in groin hernia repair in adults, the recurrence rates are considerably low (around 0.5%) [15]. Furthermore, female gender has been identified as risk factor for chronic postoperative pain following groin hernia repair [7,13]. From the view of the patients, chronic inguinal pain impairing quality of life (QOL) reflects the most relevant adverse outcome after groin hernia repair [16]. Published studies about QOL following groin hernia repair

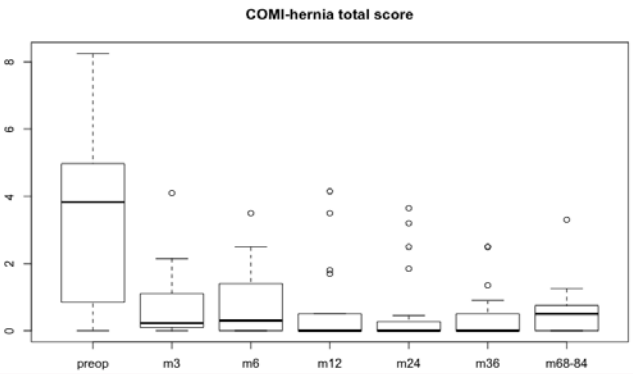

Figure 1: Boxplot of COMI-hernia total scores preoperatively (preop), after 3 months (m3), 6 months (m6), 12 months (m12), 24 months (m24), 36 months (m36), and after 68-84 months (*m68-84*).
Solid line = median, box limits = 25th and 75th percentiles, whiskers = 1.5x interquartile range (IQR), circles = maximum observations.

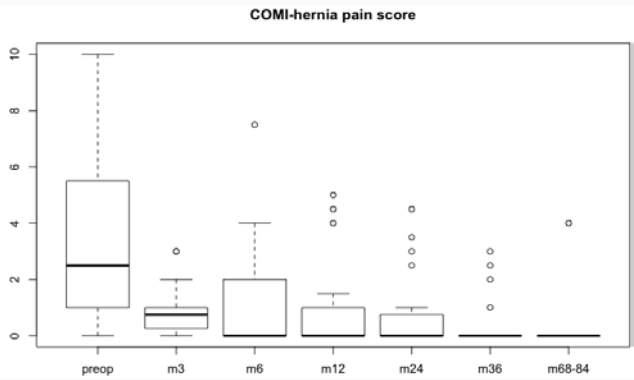

Figure 2: Boxplot of COMI-hernia pain scores preoperatively (*preop*), after 3 months (m3), 6 months (*m6*), 12 months, 24 months (*m24*), 36 months (*m36*), and after 68-84 months (*m68-84*).
Solid line = median, box limits = 25th and 75th percentiles, whiskers = 1.5x interquartile range (IQR), circles = maximum observations.

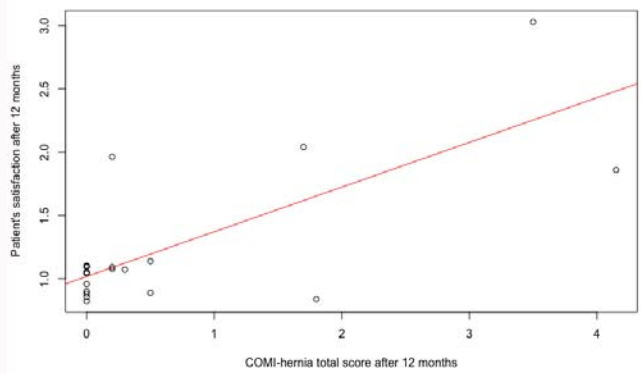

Figure 3: Patients' satisfaction versus COMI-hernia total score (after 12 months).
R^2=0.6034, p=0.00003455, coeff: 0.35255

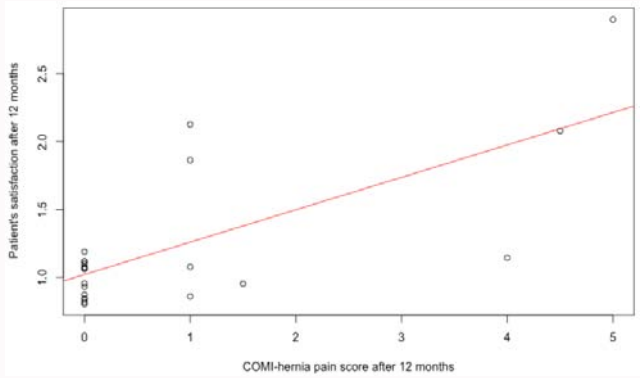

Figure 4: Patients' satisfaction versus COMI-hernia pain score (after 12 months)
R^2=0.4954, p=0.0002571, coeff: 0.238

are difficult to compare, since different tools are used to assess these outcomes [17]. We recently proposed the Core Outcome Measure Index-hernia (COMI-hernia) as such an instrument [18] and have already reported on its utility and reliability in a large cohort of male patients [19].

There is a lack of prospectively assessed, long-term follow-up data, evaluating chronic inguinal pain and QOL following groin hernia repair in women. Therefore, the primary aim of this study was to prospectively assess QOL and chronic postoperative pain following groin hernia repair in females using the COMI-hernia. The secondary goal was to identify risk factors for adverse COMI-hernia scores.

Materials and Methods

The study has been approved by the local ethics committee in Zurich (Switzerland) on January 29, 2009 (Chairperson Prof R Maurer, protocol number 22/08). All patients have given their informed consent for participation in this study. Patients were treated at four different Swiss institutions: Cantonal Hospital of Graubuenden, Hospital Maennedorf, Hospital Ilanz, and Hospital Grabs.

The inclusion criteria were as follows: ≥ 18 years of age, female gender, and diagnosis of primary groin hernia. Exclusion criteria were defined as emergent hernia repair (i.e. due to incarceration), recurrent hernia, and previous groin radiation. Each included patient completed seven questionnaires (before, as well as 3, 6, 12, 24, 36, and 68 to 84 months after surgery).

Questionnaire

The COMI questionnaire was initially developed to assess chronic back pain [20]. Subsequently, it was adapted to assess chronic pain and QOL after groin hernia repair [18]. Briefly, it assesses the following domains: pain, function, quality of live, symptom-specific well-being, work and social disability by using a graphic rating scale ranging from 0 to 10 (pain) or from 0 to 5, with higher scores representing a worse QOL and increased pain.

Operative technique

Surgeries included open repair (Lichtenstein), as well as minimal invasive techniques (Transabdominal Preperitoneal (TAPP) and Total Extra Peritoneal (TEP) inguinal hernia repair). Surgeries were performed according to the surgeon's preference. Lightweight, large pore meshes were used in all cases. All surgeries were performed under the guidance of a board-certified surgeon or by himself. To assess these putative confounding factors, surgical technique (i.e. minimal invasive versus open) and surgeon's experience were included in a linear regression analysis assessing risk factors for adverse COMI-hernia scores.

Statistics

Results are represented as median and range or as mean and

Table 1: Patients' data.

Age [years]	52.3 ± 20.3					
BMI [kg/m²]	22.9 ± 3.8					
OP time [min]	60.0 ± 24.0					
Anaesthesia	General: 20 (83%)	Spinal: 4 (17%)				
ASA score	I: 10 (42%)	II: 13 (54%)		III: 1 (4%)		
Laparoscopic vs. open procedure	Laparoscopic: 19 (79%)			open: 5 (21%)		
Groin hernia types	Direct 5 (19%)	Indirect 14 (54%)		Femoral 4 (15%)	Other 3 (12%)	
Surgeon's operative experience	0-20: 4 (17%)	21-50: 2 (8%)		51-100: 6 (25%)	>100: 12 (50%)	
Follow-up (n = 24 patients in total)	3 months: 24 (100%)	6 months: 22 (92%)	12 months: 22 (92%)	2 years: 19 (79%)	3 years: 17 (71%)	6 years 19 (79%)

Values are given as mean ± standard deviations or as absolute values plus percentages in brackets

Standard Deviation (SD). The following statistical tests were performed: Friedman rank sum test with post-hoc Wilcoxon signed rank tests (for COMI-hernia total and COMI-hernia pain scores over time). Risk factors for high postoperative COMI-hernia scores were assessed using linear regression analysis with patient's satisfaction being analysed as metric data. P-values of less than 0.05 were considered significant. The open source statistical program *R* was used for analysis. (http://www.R-project.org/).

Results

Patients' data

Twenty-four female patients with 26 hernias (two bilateral hernias) were included in this study. Patients' ages ranged from 18 to 83 years (median: 50 years). Nineteen patients (79%) had minimally invasive procedures. All patients had primary hernias. Median operation time was 53 min, ranging from 30 to 130 min. Median follow-up was 75 months, ranging from 68 to 84 months. Drop-out rates were 0% after 3 months, 8% after 6 and 12 months, 21% after 2 years, 29% after 3 years, and 21% after 75 months respectively (Table 1).

COMI-hernia total scores over time

COMI-hernia total scores were significantly lower following surgery (preoperative COMI-hernia total score of 3.24 versus COMI-hernia total score of 0.7 after 3 months: p=0.00018) (Figure 1 and Table 2). There were no differences among post-operative COMI-hernia total scores comparing the following time points: 3 months versus 6 months (p=0.53), 6 months versus 12 months (p=0.52), 12 months versus 24 months (p=0.45), 24 months versus 36 months (p=0.50), and 36 months versus 68 to 84 months (p=0.32) respectively. The highest postoperative COMI-hernia total score was observed after 6 months and the lowest after 3 years. Multivariate analysis was performed using the data from 12 months postoperatively.

COMI-hernia pain scores over time

COMI-hernia pain scores were likewise significantly lower following surgery (mean: 0.90) when compared to preoperative values (mean: 2.83) (p=0.0095) (Figure 2 and Table 3). Comparing 3 months versus 6 months (p=0.54), 6 months versus 12 months (p=0.48), 12 months versus 24 months (p=0.76), 24 months versus 36 months (p=0.55), and 36 months versus 68 to 84 months (p=0.15), COMI-hernia pain scores were not different. Similarly, as for COMI-hernia total scores, highest postoperative COMI-hernia pain scores were seen after 6 months and lowest after 68 to 84 months. As for COMI-hernia total scores, linear regression analysis was performed using the data from 12 months postoperatively.

Risk factors for high postoperative (12 months postoperatively) COMI-hernia total scores

Ten variables were included in the multivariate analysis assessing risk factors for high postoperative COMI-hernia total scores (at 12 months after surgery): American Society of Anaesthesiologists (ASA) score, Body Mass Index (BMI), surgeon's experience (i.e. number of executed hernia surgeries), age, type of anesthesia (i.e. general *vs.* spinal vs. local), surgical technique (i.e. laparoscopic vs. open), side of the hernia (i.e. unilateral vs. bilateral disease), hernia type (i.e. femoral vs. inguinal), operation time, and preoperative COMI-hernia total score. High preoperative COMI-hernia total score (p=0.045) and low ASA score (p=0.045) were identified as risk factors for high postoperative COMI-hernia total scores. Patients' satisfaction correlated with COMI-hernia total score (12 months postoperative time point used for analysis) (Figure 3) (R^2=0.6034, p=0.00003455, coefficient: 0.35255).

Risk factors for high postoperative (12 months postoperatively) COMI-hernia pain scores

The identical 10 putative risk factors for high postoperative COMI-hernia pain scores were tested with the exception of preoperative COMI-hernia pain score instead of preoperative COMI-hernia total score. Only low ASA score (p=0.038) was identified as a risk factor for high postoperative COMI-hernia pain scores (Table 4). Similarly, as for COMI-hernia total score, patients' satisfaction correlated with

Table 2: COMI-hernia scores.

	Time point	preoperatively	3 months	6 months	12 months	2 years	3 years	68 to 84 months
COMI-hernia total	Mean	3.24	0.70	0.78	0.62	0.62	0.53	0.61
	Wilcoxon signed rank test	p =0.00018		p = 0.52		p = 0.50		
			p = 0.53		p = 0.45		p = 0.32	
COMI-hernia pain	Mean	2.83	0.90	1.18	0.86	0.79	0.50	0.21
	Wilcoxon signed rank test	p =0.0095		p = 0.48		p = 0.55		
			p = 0.54		p = 0.76		p = 0.15	

COMI-hernia total and COMI-hernia pain scores preoperatively and at 3, 6, 12, 24, 36, and 68-84 months postoperatively.

Table 3: Risk factors for high COMI-hernia total scores.

Variable	Coefficient	95%-confidence interval	p-value
Preoperative COMI-hernia total score	0.44	0.099 - 0.788	0.0171
Age	0.029	-0.0175 - 0.0762	0.189
unilateral **bilateral**	0 -1.22	-4.415 - 1.971	0.409
BMI	0.0072	-0.293 - 0.0005	0.307
ASA I **ASA II** **ASA III** **ASA IV**	0 -1.488 0 0	-3.063 - 0.0877	0.0613
Operation time	-0.029	-0.111 - 0.054	0.452
Open surgery **Laparoscopic surgery**	NA NA		
Local anaesthesia **General anaesthesia** **Spinal anaesthesia**	0 0 -0.28	-2.051 - 1.494	0.731
Experience 0-20 repairs **Experience 21-50 repairs** **Experience 51-100 repairs** **Experience >100 repairs**	0 0.80 -1.71 -1.06	 -4.156 - 5.749 -5.221 - 1.973 -4.269 - 2.148	 0.724 0.298 0.474

Linear regression analysis of putative risk factors for high total COMI-hernia scores 12 month postoperatively. NA: Not Applicable; BMI: Body Mass Index; ASA: American Society of Anaesthesiologists

Table 4: Risk factors for high COMI-hernia pain scores.

Variable	Coefficient	95%-confidence interval	p-value
Preoperative COMI-hernia total	0.396	0.099 - 0.788	0.157
Age	0.024	-0.0175 - 0.0762	0.504
unilateral **bilateral**	0 -2.094	-4.415 - 1.971	0.401
BMI	0.0072	-0.293 - 0.0005	0.777
ASA I **ASA II** **ASA III** **ASA IV**	0 -1.331 0 0	-3.063 - 0.0877	0.285
Operation time	-0.026	-0.111 - 0.054	0.698
Open surgery **Laparoscopic surgery**	NA NA		
Local anaesthesia **General anaesthesia** **Spinal anaesthesia**	0 0 -0.71	-2.051 - 1.494	0.603
Experience 0-20 repairs **Experience 21-50 repairs** **Experience 51-100 repairs** **Experience >100 repairs**	0 0.932 -1.074 -0.496	 -4.156 - 5.749 -5.221 - 1.973 -4.269 - 2.148	 0.806 0.690 0.840

Linear regression analysis of putative risk factors for high COMI-hernia pain scores 12 month postoperatively. NA: Not Applicable; BMI: Body Mass Index; ASA: American Society of Anaesthesiologists

COMI-hernia pain score (12-month postoperative time point used for analysis) (Figure 4) (R^2=0.4954, p=0.0002571, coefficient: 0.238).

Discussion

To our knowledge, this is the first study, which prospectively assesses chronic postoperative pain and long-term quality of life following groin hernia repair in women using a validated questionnaire. Additionally, this study aimed to identify risk factors for an adverse outcome. QOL increased and chronic postoperative pain decreased significantly after groin hernia repair in woman measured with the COMI-hernia score (COMI-hernia total p=0.00018; COMI-hernia pain p=0.0095). No significant differences among postoperative COMI-hernia total and pain scores were observed between different time points assessed with highest scores seen 6 months postoperatively. Whereas COMI total scores remained about the same over time with similar levels after 68-84 months as e.g. after 12 months, COMI pain scores continuously (but non-significantly) decreased over time. This finding is important especially in the context of patients presenting with early postoperative pain. In our cohort of patients, a high preoperative COMI-hernia total score was identified as risk factor for high postoperative COMI-hernia total scores. Furthermore, both, COMI-hernia total and pain score were indirectly correlated with patients' satisfaction. These two findings are in line with our results from a recently published male cohort and reflect the validity of the COMI-hernia score [19].

A low ASA score was the only identified risk factor for a high postoperative COMI-hernia pain score. Young age, which is an accepted risk factor for an adverse outcome after groin hernia repair in males, did not correlate with a high COMI-hernia total or high COMI-hernia pain score. This is in contrast to our recently published male cohort.[19] One could argue that a low ASA score is mostly found in young and healthy patients and this argument could support our finding. However, a low ASA score is a statistically significant finding for an adverse outcome in our study, but the result is probably clinically irrelevant. The reason for this finding could be based on the small sample size and the fact that 96% of the patients had an ASA I or II score.

It has to be taken into consideration that women may have different risk factors for an adverse outcome after groin hernia repair then men. Unfortunately, our prospective series is too small to answer this question definitively.

Long-term follow-up in the present study was 79%. This might reflect that the COMI-hernia Questionnaire is short and easy to understand for patients. Furthermore, pre- and postoperative values may be compared [18,19,21]. This makes the COMI-hernia – at our opinion - preferable over other scores such as e.g. the Inguinal Pain Questionnaire which is longer (18 items) and only made for postoperative assessment [22].

Only a few studies focus exclusively on the treatment and outcome of groin hernia repair in women. Historically, there have been some large studies on groin hernia repair in women, which were mainly published by the Shouldice Clinic [23-29]. More recently, two larger studies from national databases were published evaluating the outcome after groin hernia repair in women [3,8]. The main outcome of these recently published studies was the recurrence rate after different surgical approaches [3,4,8-10,12,30].

The strengths of this study are the prospective study design and thus reduction of bias in comparison to most analogue studies that were performed retrospectively. A further strength is represented through the long-term and frequently performed follow-ups together with a relatively low dropout rate.

An obvious limitation of the current study is the low number and heterogeneous treatment of patients. This problem is due to the low incidence of groin hernias in women and the prospective study design. Limiting included patients to minimal invasive or open repair only would have further decreased the number of study participants. To address this issue and to estimate the impact of other possible confounding factors (such as patients' BMI, hernia type, etc.), these variables were evaluated in a multivariate analysis assessing risk factors for adverse outcome following groin hernia repair in women. Type of surgery had no effect on patients' outcome in our cohort of patients. This finding does not match with two published studies showing that an open anterior repair was associated with a higher incidence of postoperative pain compared with women undergoing a laparoscopic, total extraperitoneal repair [10,11].

Despite high preoperative COMI-hernia total and low ASA scores, none of the assessed risk factors correlated with an adverse outcome in the present study. It is questionable if accepted risk factors for males such as open repair, younger age, preoperative pain, early postoperative pain cannot be transferred one-to-one to females due to the different entity of female groin hernias (different anatomy, more femoral hernias, etc.) [31], or if our study was underpowered to show these effects. Further prospective trials are needed to assess quality of life and chronic pain in females after groin hernia repair. Due to the relative rareness of groin hernias in women, these studies should be done as multicentre trials. The COMI-hernia reflects a valuable and easy tool to assess patient outcome following groin hernia repair and should be used for such trials.

Conclusion

Non-of the known risk factors for adverse outcome (concerning quality of life and chronic pain) following groin hernia repair in males (such as young age, open repair, etc.) seem to affect the outcome in females. High quality prospective trials are needed to assess quality of life and chronic pain after groin repair in women to identify risk-factors for an adverse outcome in women.

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